

Section Clinical Research Center

Date Created: November 1st, 2010

Title: Using CRC Space

Date Reviewed/Modified: Nov. 15, 2021

SOP Number: SOP-35

Version Number: 4

PURPOSE: The purpose of this standard operating procedure (SOP) is to set guidelines for the use of Clinical Research Center (CRC) space by individuals from other University of Nebraska Medical Center (UNMC) or Nebraska Medicine (NM) departments and outside sponsor organizations.

SCOPE: This SOP applies to all UNMC or NM study personnel wanting to use the CRC for their clinical research. This SOP also applies to all sponsor representatives or Contract Research Organizations (CRO) personnel working on site.

PERSONNEL RESPONSIBLE: Principal Investigator--and when delegated by the principal investigator-- Sub-investigators, Study Coordinator and/or other pertinent staff.

DEFINITIONS:

- **Contract Research Organization (CRO)** - A person or an organization (commercial, academic, or other) contracted by the sponsor to perform one or more of a sponsor's research-related duties and functions.
- **Sponsor** - An individual, company, institution, or organization which takes responsibility for the initiation, management, and/or financing of the research.

PROCEDURES:

General Guidance –

The CRC clinical space is available for use by UNMC and Nebraska Medicine faculty and staff. Regular CRC hours are Monday-Friday, 0800-1630. Requests for use of the CRC space outside of regular CRC business hours will be considered on a case by case basis and require approval from the Director of Clinical Research Operations.

1. Use of the CRC space and resources can be requested and approved by two methods:
 - The study intake process
 - The Research Support Fund application process for Principal Investigator (PI) initiated studies. Application and instructions are available on the VCR website at <https://www.unmc.edu/cctr/resources/pilot-grant/index.html>.
2. The arrangements will be documented in writing prior to use of services.
3. All UNMC/NM study personnel using CRC space will comply with the Code of Conduct for Use of Space:

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- Coordinator will ask Clinical Research Center (CRC) personnel for a room assignment.
 - Coordinator will bring their own supplies unless permission is granted to use CRC supplies.
 - Coordinator will comply with all policies especially when it comes to patient safety policies.
 - Coordinator will clean up any space used after using it including being responsible for terminal cleaning if a participant is infected and considered contagious in any way.
 - If consenting a participant in the CRC, all coordinators should bring 2 copies of consent forms for participants so additional copies are not required to be made.
 - Any staff performing procedures in the CRC space must be credentialed by Nebraska Medicine.
 - If staff outside of the CRC are performing any invasive procedures including phlebotomy, a CRC nurse must also be present, in case of an emergency.
4. Sponsor representatives or CRO personnel, i.e. study monitors are only permitted to work during regular CRC business hours when CRC staff is present. CRC personnel will assign sponsor representative/study monitors a work area in the designated monitor spaces in Eppley Cancer Institute and make sure they have access to only requested study subject information for their visit.

Report suspicious activity or problems to security by calling 559-5111 Study coordinators from other UNMC/NM departments are not to leave their subjects unattended unless it was arranged for CRC personnel to be back-ups for the study and CRC personnel are notified that they will be leaving the area.

Resources:

Study Intake Process: <https://www.unmc.edu/ctr/resources/crc/intakeform.html>



**Center for Clinical and
Translational Research
Standard Operating Procedure**



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Staff Accountability:

Developed By: Director of Clinical Research Operations, Clinical Research Center
Associate Vice Chancellor for Clinical Research, Clinical Research Center

Reviewed By: Research Nurse Coordinator, Clinical Research Center

Department Approval

Signed *LuAnn Larson*
Director of Clinical Research Operations

Signed *Matt Lunning*
Medical Director of Clinical Research Center









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Final Audit Report

2021-11-18

Created:	2021-11-15
By:	Charles Miller (charles.miller@unmc.edu)
Status:	Signed
Transaction ID:	CBJCHBCAABAAAtJtVwZCoeX9XAikS5_u6AhHGB3ZYVZJ2

"CRC-SOP-35-UsingCRCSpace" History

-  Document created by Charles Miller (charles.miller@unmc.edu)
2021-11-15 - 10:18:23 PM GMT- IP address: 192.94.102.5
-  Document emailed to LuAnn Larson (llarson@unmc.edu) for signature
2021-11-15 - 10:18:48 PM GMT
-  Email viewed by LuAnn Larson (llarson@unmc.edu)
2021-11-15 - 10:19:06 PM GMT- IP address: 34.127.33.148
-  Document e-signed by LuAnn Larson (llarson@unmc.edu)
Signature Date: 2021-11-15 - 10:19:25 PM GMT - Time Source: server- IP address: 34.127.33.148
-  Document emailed to Matt Lunning (mlunning@unmc.edu) for signature
2021-11-15 - 10:19:27 PM GMT
-  Email viewed by Matt Lunning (mlunning@unmc.edu)
2021-11-15 - 10:45:10 PM GMT- IP address: 192.94.102.15
-  Document e-signed by Matt Lunning (mlunning@unmc.edu)
Signature Date: 2021-11-18 - 7:58:08 PM GMT - Time Source: server- IP address: 184.97.164.166
-  Agreement completed.
2021-11-18 - 7:58:08 PM GMT